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| 10/822,496      | 04/12/2004  | Larry F. Lemanski    | 6818-70             | 3665             |

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EXAMINER

TSAY, MARSHA M

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1656

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



Art Unit: 1656

This Office action is in response to Applicants' remarks received October 2, 2006.

Applicants' remarks have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Objections and/or rejections not reiterated from previous Office actions are hereby withdrawn.

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

Claims 8-9 are canceled. Claims 5, 15-24 are withdrawn. Claims 1-4, 6-7, 10-14 are currently under examination.

Priority: The priority date is April 10, 2003.

### **Objections and Rejections**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 3 is drawn to a purified nucleic acid comprising a nucleotide sequence that is transcribed into a MIR molecule as identified by SEQ ID NOS: 1 or 5 wherein said nucleic acid

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molecule further comprises a nucleotide sequence whose complement hybridizes under low, moderate or high stringent hybridization conditions to the nucleotide sequence of at least one of SEQ ID NO: 2 and SEQ ID NO: 3. The claim is directed to numerous complementary DNA molecules that hybridize under low, moderate or high stringent hybridization conditions. The claim does not recite any functional language.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The instant claim is drawn to a purified nucleic acid comprising a nucleotide sequence that is transcribed into a MIR molecule as identified by SEQ ID NOS: 1 or 5 wherein said nucleic acid molecule further comprises a nucleotide sequence whose complement hybridizes

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under low, moderate or high stringent hybridization conditions to the nucleotide sequence of at least one of SEQ ID NO: 2 and SEQ ID NO: 3. The claim recites no functional language and would require undue experimentation for one of ordinary skill in the art to make and/or use the claimed invention. Undue experimentation would be expected because: 1) the quantity of experimentation required to produce all nucleic acids further comprising complementary DNAs to SEQ ID NO: 2 and/or 3 is substantial, 2) the amount of guidance given in the specification in order to make or use the claimed invention is insufficient, 3) the working examples are just a fraction of what might encompass complementary DNA molecules that hybridize to SEQ ID NO: 2 and/or 3 under low, moderate, and stringent hybridization conditions 4) the nature of the invention is such that it is non-trivial and requires considerable experimentation and time to determine complementary DNA molecules that hybridize to SEQ ID NO: 2 and/or 3 under low, moderate, and stringent hybridization conditions, 5) the state of the prior art does not aid one of ordinary skill in the art as to the function of the DNA molecules, 6) the relative skill of those in the art, although at a high level, would still require assistance and detailed guidance so as to make and/or use the claimed invention without undue experimentation, 7) the uncertainty of success for each step in producing DNA molecules that will have functional activity is considerable, 8) the breadth of the claims are too broad so as to allow one of ordinary skill in the art to reproduce, make and/or use the claimed invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

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claimed invention. The claim is drawn to a purified nucleic acid comprising a nucleotide sequence that is transcribed into a MIR molecule as identified by SEQ ID NOS: 1 or 5 wherein said nucleic acid molecule further comprises a nucleotide sequence whose complement hybridizes under low, moderate or high stringent hybridization conditions to the nucleotide sequence of at least one of SEQ ID NO: 2 and SEQ ID NO: 3. On page 5 lines 18-25, the specification discloses low stringency conditions have wash conditions at 50°C. The claim is directed to numerous complementary DNA molecules that hybridize under low stringent conditions.

The specification does not contain any disclosure of the function of all DNA sequences that further comprise a nucleotide sequence whose complement hybridizes under low hybridization conditions to the nucleotide sequence of at least one of SEQ ID NO: 2 and SEQ ID NO: 3. The genus of DNAs that hybridize to SEQ ID NO: 2 or 3 under low stringent conditions is a large variable genus with the potentiality of encoding many different proteins and/or transcribing into many different RNA molecules. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences.

The specification does not disclose species of the claimed genus; and therefore, does not put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-7, 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3 are indefinite because it is unclear whether MIR has SEQ ID NO: 1 or 5 or whether the nucleotide transcribing MIR has SEQ ID NO: 1 or 5.

Claims 2, 7 are included in this rejection because it is dependent on claim 1.

Claims 4 and 6 are drawn to a purified nucleic acid comprising a nucleotide sequence that is transcribed into a MIR molecule of SEQ ID NO: 1 and 5, respectively. The claims are indefinite because it is unclear whether the MIR molecule has SEQ ID NO: 1 or 5 or whether the nucleotide transcribing MIR has SEQ ID NO: 1 or 5.

Claim 10 recites a ribonucleic acid sequence which is complementary to a deoxyribonucleic acid sequence. It is unclear if the RNA is fully or partially complementary to the DNA.

Claims 11-12 are included in this rejection because they are dependent on claim 10.

Claims 13-14 are allowed.

The instant claims appear to be free of art.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

December 6, 2006

*M. Monshipouri*  
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**PRIMARY EXAMINER**